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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,761	02/07/2002	Clark T. Hung	20076.73	7596

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,761	HUNG ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 31-61* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 30 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. Note instant claim 30 depends from both claims 29 and 1 which is improper.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-29 and 31-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 61 recite that the device includes "means for applying hydrostatic fluid pressure and/or strain-controlled deformational loading via loading platens". This language is indefinite because it cannot be clearly determined if the recited loading platens apply both the recited hydrostatic fluid pressure and strain-controlled deformational loading or just the strain-controlled loading. Review of the instant specification would indicate that the platens merely apply the strain-controlled loading. As a result, the claim could be interpreted as a device that only includes a "means for applying hydrostatic loading" in view of the use of the

language "and/or" in the claim. Clarification and/or correction is requested. The similar indefiniteness applies to independent method claim 29.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-6 and 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Peterson et al.(US 6,121,042).

With respect to claim 1, the reference of Peterson et al. discloses a bioreactor device that includes a growth chamber (10, 50, 100, 150) and means for applying hydrostatic (18,30) fluid pressure to a cell-seeded scaffold (20) held within the growth chamber. Note structures (18, 30) are capable of applying hydrostatic fluid pressure to cell-seeded scaffolds in the manner recited in the wherein clause of the claim. The claim does not include any positively recited structural

elements such as a control device for the means or devices applying the pressure or load to the cell-seeded scaffolds.

With respect to claims 2-5, the growth chamber is capable of holding any type of scaffold material. Note claim 1 does not positively recite the scaffold as part of the claimed device.

With respect to claim 6, pump (30) can provide pulsatile flow (See column 4, line 66, to column 5, line 12).

With respect to claims 22-25, in the absence of further positively recited structure, the device would be capable of providing the claimed tissue.

With respect to claims 26 and 27, the device supports the scaffolds within the growth chambers with holding means so as to produce a tissue of a desired shape of a body part to be replace and/or repaired.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al.(US 6,121,042).

The reference of Peterson et al. has been discussed above.

While the reference of Peterson et al. disclose the use of cyclic hydrostatic pressurization loading of the construct held within the growth chamber, the reference is silent as to the specifics of the cyclic treatments in terms of pressures, frequency and/or length of time.

The reference of Peterson et al. discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired (See column 6, lines 63-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.

10. Claims 1-29, 31-44 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fofonoff et al.(US 5,882,929) in view of Peterson et al.(US 6,121,042).

With respect to claim 1, the reference of Fofonoff et al. discloses a bioreactor device that includes a growth chamber (44) and means for applying deformational loading (72, 14) to a cell-seeded scaffold (26, 30) held within the growth chamber.

Claims 1 and 29, as well as claims 6, 20, 36, 37 and 38, differ because they require that the device and method of use includes a means and step for hydrostatic loading of the scaffold material.

The reference of Peterson et al. discloses that it is known in the art to provide a bioreactor device with both a means for deformational loading and hydrostatic loading of tissue constructs within the bioreactor chamber. Specifically, the reference of Peterson et al. discloses a bioreactor device that includes a growth chamber (10, 50, 100, 150) and means for applying hydrostatic (18,30) and deformational loading (12, 54, 56, 154) to a cell-seeded scaffold (20) held within the growth chamber.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Fofonoff et al. in include hydrostatic loading as suggested by Peterson et al. for the known and expected result of providing an additional means recognized in the art for ensuring that the cultured cells are exposed to conditions that mimic physiological conditions and for improving the contact of the culture medium within in pores of the porous scaffold material during the culture process. Note structures (18, 30) are capable of applying hydrostatic fluid pressure to cell-seeded scaffolds in

the manner recited in the wherein clause of the claim. The claim does not include any positively recited structural elements such as a control device for the means or devices applying the pressure or load to the cell-seeded scaffolds.

With respect to claims 2-5, the growth chamber is capable of holding any type of scaffold material. Note claim 1 does not positively recite the scaffold as part of the claimed device.

With respect to claims 7-12 and 39-44, while the reference of Peterson et al. disclose the use of cyclic hydrostatic pressurization and/or loading of the construct held within the growth chamber, the reference is silent as to the specifics of the cyclic treatments in terms of pressures, deformation, frequency and/or length of time.

The reference of Peterson et al. discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired (See column 6, lines 63-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.

With respect to claim 13, the device is also capable of applying an intermittent cyclic strain-controlled deformational loading (See column 8, lines 18-38).

With respect to claims 14-19, while the reference of Fofonoff et al. disclose the use of cyclic loading of the construct held within the growth chamber, the reference is silent as to the specifics of the cyclic treatments in terms of pressures, deformation, frequency and/or length of time.

The reference of Fofonoff et al. discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired (See column 2, lines 30-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time. Note the end result is that the structure of the loading device of Fofonoff et al. is capable of providing the strain-controlled loading recited in the device claims.

With respect to claim 21, the reference of Peterson et al. discloses that it is known in the art to a modify the loads over time in response to changes in the density of the construct (See column 7, lines 1-5). As a result, it would have been obvious to one of ordinary skill in the art to modify the loads of the modified primary reference over time for the known and expected result of responding to changes in the density of the tissue construct during the culture process.

With respect to claims 22-25, in the absence of further positively recited structure, the device would be capable of providing the claimed tissue.

With respect to claims 26-28 and 58-60, the device supports the scaffolds within the growth chambers with holding means so as to produce a tissue of a desired shape of a body part to be replace and/or repaired. (See the platens 14 and 22).

With respect to claims 29 and 61, the bioreactor contains scaffold material is impregnated with chondrocyte cells (See column 2, lines 30-44).

With respect to claims 31, 32 and 34, the reference discloses the use biocompatible and bioabsorbable materials (See column 2, lines 20-29).

With respect to claim 35, the resulting constructs mature into replacement cartilage tissue (See column 2, lines 44-52).

With respect to claim 33, while the reference of Fofonoff et al. prefers to use bioadsorbable material, the use of synthetic biocompatible material is known (See column 1, lines 28-35). As a result, it would have been obvious to one of ordinary skill in the art to use synthetic material for the scaffold for the known and expected result of providing an alternative means recognized in the art to achieve the same result, supporting the cultured tissue for implantation.

With respect to claims 54-57, while the reference is silent as to the specific cartilage produced, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the specific type of cartilage produced based merely on the intend use of the cartilage in terms of the location in the body it is intended to be implanted.

Allowable Subject Matter

11. Claims 45-53 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to teach or fairly suggest a method of producing functional cartilaginous tissue as recited in the claims wherein the use of strain-controlled loading of the scaffold via loading platens according to a loading regime optimized for cartilaginous tissue growth.

Response to Arguments

13. Applicant's arguments filed 23 June 2004 have been fully considered but they are not persuasive.

Applicants argue that the rejection of the claims over either of the references of Peterson or Fofonoff alone or in combination is improper for the following reasons:

Both the references of Peterson and Fofonoff are directed to "load or force control" while the instant invention is directed "strain-controlled deformation" which applicants go into great detail in the remarks section at pages 16-18.

Applicants' arguments are not found to be persuasive for the following reasons:

Independent claims 1, 29 and 61 are not even limited to a device and/or method that requires the "strain-controlled deformational loading" discussed at length by Applicants. Note claims 1, 29 and 61 employ the language "and/or" which implies the claims can be interpreted to encompass a device or method that only requires a means or step for applying hydrostatic fluid pressure. As recited in the prior art rejections of record, the reference of Peterson et al. discloses a bioreactor device for exposing cell-seeded scaffolds to controlled hydrostatic fluid pressure.

With respect to the "wherein" clause added to claims 1 and 61, the structures for applying

the hydrostatic fluid pressure disclosed by the prior art are capable of providing a loading regime optimized for cartilaginous tissue growth.

With respect to device claims 13-12 and 28, while the loading platens of the reference of Fofonoff are not specifically disclosed as applying a "strain-controlled deformation" to the scaffold material, these structures are capable of applying a "strain-controlled" deformational loading to the scaffolds. The instant device claims are silent as to any type of positively recited structure that controls the loading devices so as to apply the desired optimal conditions in terms of "strain-controlled deformation" as argued by applicants.

Note the method claims that limit the invention to include the "strain-controlled" deformation have been indicated as being allowable over the prior art of record.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

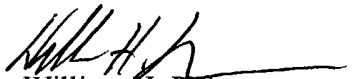
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB